SUPPORTING STATEMENT FOR INFORMATION COLLECTION REQUEST (ICR)

1. IDENTIFICATION OF THE INFORMATION COLLECTION

(a). **TITLE: APPLICATION FOR EXPERIMENTAL USE PERMIT (EUP) TO SHIP AND USE A PESTICIDE FOR EXPERIMENTAL PURPOSES ONLY**

OMB NO.: 2070-0040

EPA NO.: 0276.07

(b). Characterization

The Environmental Protection Agency (EPA) is the principle federal agency charged with the regulation of pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended. FIFRA section 5 authorizes the pesticide companies temporarily to ship pesticide products for experimental use for the purpose of gathering data necessary to support the application for registration of a pesticide product. In general, EUPs are either issued for a pesticide not registered with the Agency or for a registered pesticide for a use not registered with the Agency.

The information collected and reported under an EUP is a summary of what is routinely submitted in connection with registration. The EUP allows for large scale field testing, if necessary, in order to collect sufficient data to support registration. An EUP is not required if the person conducting the tests does not expect to receive benefits in pest control.

EPA Form 8570-17, Application for an Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only, is filed by the prospective registrant for a permit to generate information or data necessary to register a pesticide under Section 3 of FIFRA. This information from the applicant is necessary in order to grant and effectively monitor the EUP. Beyond the information as supplied on EPA Form 8570-17, is a final report on the results of the experimental program which includes information such as: amount of the product applied; the crops or sites treated; any observed adverse effects; any adverse weather conditions which may have inhibited the program; the goals achieved; and the disposition of containers, unused pesticide material, and affected food/feed commodities.

Title 40 of the Code of Federal Regulations (CFR)Part 172, Microbial Pesticides; Experimental Use Permits and Notifications includes a requirement for the submission and review of Notifications prior to any introduction into the environment of certain genetically modified microbial pesticides. A

Notification is a document which informs the Agency of proposed small-scale testing in the environment with certain kinds of microbial pesticides. The notification must be submitted directly to the Agency at least 90 days prior to the proposed small-scale test to allow EPA to evaluate the proposed tests. Contained testing facilities will also be responsible for maintaining records describing containment and inactivation controls for the same subset of genetically modified microbial pesticides; these records would demonstrate that the research was performed under contained conditions.

2. NEED FOR AND USE OF THE COLLECTION

2(a). Need/Authority for the Collection

As required by section 5 of FIFRA and Part 172 of 40 CFR (attached), the information collected and reported is necessary to evaluate the potential hazard of the product and to make certain that the permit was issued for genuine experimental purposes rather than as a form of temporary registration. To ensure compliance, the final report is compared with the objectives of the testing program. The information also enables EPA to identify whether the treated food or feed crops will be used in a commercial market which would require issuance of a temporary tolerance or destroyed because the use was for research purposes only. Since it is common for applicants to request extensions of EUP's, it is imperative that the Agency has reports in hand in order to judge the need for such extensions.

Under the existing EUP regulations, small-scale experimental uses of pesticides are presumed exempt from the EUP requirements. Tests conducted on ten acres or less of land involving use of the test material against a particular pest would be exempt, provided that any food or feed crops involved in or affected by the tests are destroyed or consumed only by experimental animals or unless a tolerance or exemption from a tolerance has been established. Also, tests conducted on a total of not more than one surface-acre of water involving use of a test material against a particular pest would be exempt, provided such waters involved in or affected by the tests will not be used for irrigation, drinking water supplies, or body contact recreational activities. In addition, no tests may be conducted in waters that contain, or which affect any fish, shellfish, or other plants or animals which may be taken and used for food or feed unless a tolerance or exemption from a tolerance has been established.

However, since the issuance of the EUP regulations in 1975, new and different microbial pesticides have been developed that warrant a closer review at the small-scale testing stage. Specifically, the Agency believes that certain microbial pesticides are sufficiently different from conventional chemical

pesticides and other microbial pesticides that they warrant EPA oversight before they are released in the environment.

Microbial pesticides may now be developed such that new pesticidal properties are imparted or existing pesticidal properties are directly or indirectly affected, allowing for significantly new or expanded host ranges, new or enhanced toxin production, and new fitness or survivability characteristics. These microbial pesticides also may be modified so that the genetic components responsible for the added or altered pesticidal properties may be mobile under environmental conditions, which could allow for transfer of the pesticidal traits to other organisms that would otherwise be unable or unlikely to acquire these properties. The Agency believes that some of these microbial pesticides have the potential to pose risks when used in small-scale testing and, therefore, warrant an assessment before use in the environment.

The Agency does not require notification for testing conducted in facilities in which there are adequate containment and inactivation controls. Selection and use of specific containment and inactivation controls is at the discretion of the individual or institution conducting the test and must take into account the microorganism's ability to survive in the environment, potential routes of release, and procedures for transfer of materials. The proposal requires that records be kept to describe the controls and show that they are used. This is consistent with current standard research practices.

2(b). Use/Users of the Data

The information collected and reported under an EUP will enable the Agency to:

- o judge whether a renewal, extension or amendment of the EUP, if requested, is justified;
- o allow for adequate monitoring of the EUP program; and
- o ascertain the cause/effect relationship when a pesticide is registered and later found to have adverse effects (as in the case of phytotoxicity).

Efficacy data are also furnished to the Agency when products being tested are important to public health; such as products to control microorganisms infectious to man and vertebrates that may transmit diseases to humans.

In regards to biological pesticides, upon receipt of a notification, OPP uses the submitted information as the basis for its scientific evaluation of potential risks to human health and the environment that may be presented by the proposed test in

order to determine whether an EUP is required. For each notification, the Agency may make one of the following decisions:

a. approve the proposed test to proceed without an EUP;
b. disapprove the proposed test;
c. require additional information; or
d. require an EUP for the small-scale test.

The containment and inactivation records will be made available for inspection and/or submitted at the Agency's written request. EPA may review as needed these records to ensure that the controls are adequate. The Agency may require changes to the containment and inactivation controls after review of the records. If these changes are not made, a notification would be necessary.

3. THE RESPONDENTS AND THE INFORMATION REQUESTED

3(a). Respondents/SIC Codes

The three-digit SIC codes for the businesses and other institutions participating in this program are 286 and 287.

Additionally, businesses which develop and market genetically modified microorganisms used as pesticides are some of the respondents to this information collection activity as well as university and other research facilities. The SIC codes assigned to these businesses and other institutions responding are: 286 (Industrial Organic Chemicals), 287 (Agricultural Chemicals), 8733 (Non-Commercial Research Organizations) and 2881 (Colleges, Universities, and Professional Schools).

3(b). Information Requested

(i) Data Items

Application for an experimental use permit requires specific information to be completed on EPA Form 8570-17:

(1) Item 1: Type of Application - informs the Agency whether the application is either new, an amendment, or for an extension of a previously approved EUP. If it is a previously-approved EUP, the identifying permit number assigned must be indicated.

(2) Item 2: Briefly explain - if application is an amendment, provides the Agency with a brief explanation of the modification to the previously-approved EUP.

(3) Item 3: Name and Address of Firm/Person to Whom the Experimental Use Permit is to be Issued - provides the Agency with a record of the party responsible for the

experiment and the identifying EPA company, when applicable.

(4) Item 4: Name and Address of Shipper - provides the Agency with a record of the party responsible for any transportation of the material.

(5) Item 5: Name of Product - self-explanatory.

(6) Item 6: Is Product Registered with EPA - allows the Agency to determine if the permit is for a new pesticide, or for a new use of a known pesticide.

(7) Item 7: Total Quantity of Product Proposed for Shipment/Use - informs the Agency of the amount of the formulated product and of the active ingredient (in pounds) that will be produced, shipped, and used.

(8) Item 8: Acreage or Area to be Treated - informs the Agency of the number of acres to be treated in the area of experimental use.

(9) Item 9: Proposed Period of Shipment/Use - informs the Agency when the experiment will take place.

(10) Item 10: Places from which Shipped - informs the Agency of the locations where the pesticide may be shipped from and through.

(11) Item 11: Crop/Site to be Treated - informs the Agency of the kinds of crops and location sites in which the program will be conducted.

(12) Item 12: Specify the Name and Telephone Number of the Contact Person Most Familiar with this Application - self-explanatory.

(13) Item 13: Signature of Applicant or Authorized Firm Representative - self-explanatory.

(14) Item 14: Title - self-explanatory.

(15) Item 15: Date Signed - self-explanatory.

The information areas to be addressed in a notification in regards to genetically modified microbial pesticides are identified in section 172.48. The information to be provided for a specific notification will vary depending on the particular microbial pesticide and how it has been modified, as well as the manner in which it is to be used in the environment. Key areas to be addressed in a notification include the identity of the

microbial pesticide and description of the natural habitat of the parental strain(s), information on host range (if any) and survival, the methods and manner in which the microorganism has been modified, and a description of the proposed testing program for the microbial pesticide. In general, this is information that the individual already will have obtained during the course of product research and development.

The types of information to be maintained for containment records are set forth in section 172.45. This provision does not require data to be developed, but rather that records be kept to verify containment procedures as is done as a matter of standard research practice.

(ii) Respondent Activities

The following are the activities to be conducted by a representative respondent (applicant) in order to comply with the provisions of EPA Form 8570-17.

Activity	Explanation
read regulations, including FIFRA Section 5 and 40 CFR 172.8(b)	become familiar with the legislation and regulations and determine the requirements as they pertain to a proposed experimental use of a pesticide
plan activities	plan the actions necessary to comply with the legislation and regulations
create information	develop information required for notification
gather information	gather information required for the notification or containment records
process, compile, and review information	check information for accuracy and completeness
complete paperwork	prepare notification document or containment record

record, disclose, and display information	submit notification to OPP
store, maintain, and file information	retain copies of all submissions

4. THE INFORMATION COLLECTED--AGENCY ACTIVITIES, COLLECTION METHODOLOGY, AND INFORMATION MANAGEMENT

4(a). Agency Activities

The following are activities necessary to evaluate a submitted request for an experimental use permit:

Activity	Explanation
review submitted application package and/or notifications	review application form and package for completeness and appropriateness
record submission	record submission in tracking system
analyze submission	conduct scientific reviews of data
answer registrants' questions	respond to any questions either verbally or in writing
file submission	store and maintain submission information in Agency files system

4(b). Collection Methodology and Management

The submitted EUP package includes EPA Application Form 8570-17, the product label, and, in most cases, supporting data. The application form and the product label are pin-punched by date by the Front-End Application Processing Unit for initial screening. If everything is found to be complete, the proposed EUP is given a file symbol, entered into the Pesticide Regulatory Action Tracking System (PRATS), and a registration jacket is created identifying the document by the appropriate Product

Manager (PM) for the chemical being employed. The accompanying data is identified and processed for review.

The three-part EUP package is sent to the designated PM who is responsible for managing the registration action. The testing program and labeling program are reviewed by the PM while the data portion is routed for scientific review to the appropriate discipline. On completion of the scientific review, the PM receives a written analysis of the data. If the data is found to be acceptable, an EUP is issued. If not, the EUP request is rejected and the PM then notifies the applicant in writing of the deficiencies before the EUP request can be resubmitted. The file is then updated in the tracking system to reflect the latest status and the registration jacket is stored in the file room.

Toward this end, the Agency has identified the minimum amount of data to be submitted to permit a scientific assessment of the proposed research. Much of this information already would be available to the respondent as part of the normal information developed during the research and development stage. These data requirements are flexible and may be adjusted as appropriate to the specific product under review. Finally, all of the information submitted in support of a notification is also relevant to support approval of an EUP for large-scale testing and EPA will refer to the data already on hand.

As an alternative to submitting a Notification, an applicant may apply for, and obtain an EUP before conducting a small-scale field test with a genetically modified microbial pesticide. In some instances the data required are specific to the microorganism and field test being proposed. However, for some data requirements, information on related microorganisms may be a suitable alternative to submitting data derived solely from tests conducted with the microorganism to be tested. These determinations are made on a case-specific basis.

4(c). Small Entity Flexibility

The Agency recognizes that many small businesses are involved in research and development activities with pesticides. In setting forth the notification requirements, EPA has sought to minimize the regulatory burden on research and development. Toward this end, the Agency has identified the minimum amount of data to be submitted to permit a scientific assessment of the proposed research. Much of this information already would be available to the respondent as part of the normal information developed during the research and development stage. These data requirements are flexible and may be adjusted as appropriate to the specific product under review. As an alternative to submitting a Notification, an applicant may apply for, and obtain an EUP before conducting a field test with a pesticide. Because

the notification requirements have been designed from the outset to minimize the burden on respondents, as a result, there are no special measures taken for small businesses since already the burden is considered to be at a minimal level.

4(d). Collection Schedule

Not applicable. This activity is conducted only when an EUP or notification request is made.

5. NONDUPLICATION, CONSULTATIONS, AND OTHER COLLECTION CRITERIA

5(a). Nonduplication

The respondent is not required to submit any sort of EUP-related information or data to any other Federal agency or to any other EPA program offices. However, in instances where a microbial pesticide may be considered a plant pest, the respondent will need to contact the U.S. Department of Agricultures's Plant and Animal Health Inspection Service for a determination of whether the microbial pesticide is a plant pest and the need for a permit.

FIFRA section 7 (attached), however, does require annual pesticide production reports from all persons who produce pesticides. The pesticide material produced in conjunction with an EUP would be included in these annual production reports; however, annual production information is not required as a condition of the EUP, only total production in the final report.

5(b). Consultations

Consultation and/or dialogue between the respondent and EPA occurs on an informal, ongoing "as needed" basis, primarily during the submission and review of the application for an experimental use permit. The experience has been that if any sort of problem, such as technical, administrative, or otherwise arises, the respondent is given ample opportunity to inform the agency and vice versa. This communication between both parties may take place either in a telephone conversation or in a meeting setting, but not necessarily by a prescribed schedule.

5(c). Effects of Less Frequent Collection

There is only one submission required in conjunction with each request for EPA approval to conduct testing on certain pesticides. Therefore, the frequency of the collection cannot be reduced, except to eliminate the collection altogether. The Agency then would have no means by which to evaluate the

potential human health risks and environmental hazard presented by the chemicals in a proposed test.

5(d). General Guidelines

The only guideline under the Paperwork Reduction Act (PRA) that is exceeded in this collection is the time period for retaining records. EPA requirements in 40 CFR 169.2(k) state that records containing research data relating to registered pesticides be retained as long as the registration is valid and the manufacturer remains in business. Pesticide registrations are valid until they are either voluntarily cancelled or withdrawn by the registrant or until EPA has cause to suspend or cancel the registration. Since the average period of marketability of a pesticide ranges from 15 to 30 years, the PRA guidelines specifying that data other than health, medical, or tax records not be required to be retained for more than three years will be exceeded in this program.

5(e). Confidentiality and Sensitive Questions

(i) Confidentiality

Although the EPA urges the submitter to minimize the amount of claimed Confidential Business Information (CBI), all data/information brought to the Agency in conjunction with a notification may be claimed as a trade secret or commercial or financial information and will be protected from disclosure by the EPA under FIFRA § 10 and the Agency's confidentiality regulation (Title 40 CFR Part 2, Subpart B).

When trade secret information or Confidential Business Information (CBI) is provided to the Agency, such information is protected from disclosure under FIFRA Section 10, as amended and EPA's confidentiality regulation, Title 40 CFR, Subpart B) (attached). Data submitted to the Agency are handled strictly in accordance with the **FIFRA CBI Security Manual**. This manual contains instructions relative to all contact with confidential documents, including responsibility of EPA employees; physical security measures; CBI materials within EPA, such as CBI typing procedures (documents typed internally or on contract); and division internal procedures. The manual dictates that: (1) all CBI must be marked or flagged as such , (2) all CBI must be kept in secure (double-locked areas, and (3) all CBI for destruction must be cleared by a document control officer and placed in the Office of Prevention, Pesticides and Toxic Substances paper shredder.

(ii) Sensitive questions

No information of a sensitive or private nature is requested in conjunction with this information collection activity. Further, this information collection activity complies with the provisions of the Privacy Act of 1974 and OMB Circular A-108.

6. ESTIMATING THE BURDEN AND COST OF THE COLLECTION

6(a). Estimating Respondent Burden

Based on the respondent activities identified in section 3(b)(ii) above, the burden hours exhibited on the Master Table in section 6(d) were developed to represent a typical respondent to the notification and containment recordkeeping requirements. Respondent burden hours are estimated at 10.10 hours per respondent at a cost of $341.90. The total number of expected respondents is 100. The total respondent burden hour is 1,010 hours. Separate tables are included for the Notifications for small-scale testing of genetically modified microbial pesticides. Initial notifications are estimated to take 78 hours with an estimted 6 respondents per year costing $6,221 per applicant. Resubmission Notifications are estimated at 42 burden hours per respondent, estimating two respondents per year, costing $3,074 per notification.

6(b). Estimating Respondent Costs

The total estimated respondent (applicant) burden to comply with the EUP aspect of this information collection activity, based on 100 respondents annually, is 1,010 hours, estimated to cost $75,790.

ANNUAL RESPONDENT BURDEN/COST ESTIMATES

	Burden Hours (per year)			**TOTAL**	
COLLECTION ACTIVITIES	Mgmt. $114/hr.[1]	Tech. $77/hr.	Clerical $35/hr.	Hours	Costs
Read regulations	0.5	0.5	0.0	1.00	$95.50
Plan activities	0.0	1.0	0.0	1.00	$77.00
Create information	0.0	2.0	0.0	2.00	$154.00
Gather information	0.0	2.5	0.0	2.50	$192.50

Compile and review	0.0	2.0	0.0	2.00	$154.00
Complete paperwork	0.1	0.5	0.0	0.60	$49.90
Store/maintain data	0.0	0.0	1.0	1.00	$35.00
TOTAL	0.60	8.50	1.00	10.10	$757.90

ANNUAL BURDEN:10.10 Total Hours x 100 Respondents= 1,010 Hours

ANNUAL COSTS
(a) Management: 0.6 hours x $114 x 100 Respondents = $ 6840
(b) Technical: 8.50 hours x $77 x 100 Respondents = $65450
(c) Clerical: 1.00 hours x $35 x 100 Respondents = $ 3500
Total = $75790

The total estimated respondent (applicant) burden to comply with the Notification aspect of this information collection activity, based on 6 initial respondents and 2 respondents for resubmission notifications annually, is 552 hours, estimated to cost $40,294.

Annual *Respondent* **Burden/Cost Estimates for Initial Notifications**

	Burden Hours (per year)			**Total**	
Collection Activity	**Mgmt $114 hr**	**Tech. $77 hr**	**Clerical $35 hr**	**Hours**	**Costs**
read regulations	5	2		7	$724
plan activities	2	10		12	$998
create information	5	5		10	$955
gather information		10		10	$770
process, compile and review information		5	5	10	$560
complete paperwork	5	5	10	20	$1305
record, disclose & display information		2	3	5	$259
store, maintain and file the information			4	4	$140
TOTAL	17	37	24	78	$5711

ANNUAL BURDEN: 78 Hours Total x 6 respondents = 468 hours

ANNUAL COSTS: $5711 total costs x 6 respondents = $34266

Annual *Respondent* **Burden/Cost Estimates for Resubmission Notifications**

	Burden Hours (per year)			Total	
Collection Activity	**Mgmt $114 hr**	**Tech. $77 hr**	**Cler. $35 hr**	**Hours**	**Costs**
read regulations					
plan activities	2			2	$228
create information		12		12	$924
gather information		6		6	$462
process, compile and review information		3		3	$231
complete paperwork		7	3	10	$644
record, disclose & display information		5	3	8	$490
store, maintain and file the information			1	1	$35
TOTAL	2	33	7	42	$3014

ANNUAL BURDEN: 42 Hours Total x 2 respondents= 84 hours

ANNUAL COSTS: $3,014 total costs x 2 respondents = 6,028

Total *Respondent* **Burden/Cost Estimates for Verification of Containment**

	Burden Hours (per year)			Total	
Collection Activity	**Mgmt.**	**Technical**	**Clerical**	**Hours**	**Costs**
read regulations					

plan activities					
create information		4			$220
gather information					
process, compile and reveal information					
complete paperwork		2			$110
record, disclose & display information					
store, maintain and file the information					
TOTAL		6			$330

*** These are record-keeping costs**

6(c). Estimating Agency Burden and Costs

ANNUAL AGENCY BURDEN/COST ESTIMATES FOR EUPs

	Burden Hours (per year)			**TOTAL**	
COLLECTION ACTIVITIES	Mgmt. $76/hr.	Tech. $55/hr.	Cler. $25/hr.	Hours	Costs
Review submitted application package	0.0	2.0	0.0	2.00	$110.00
Record submission	0.0	1.0	0.0	1.00	$55.00
Analyze submission	1.0	8.0	0.0	9.00	$516.00
File submission	0.0	2.0	1.0	3.00	$135.00
TOTAL	1.00	13.00	1.00	15.00	$816.00

ANNUAL BURDEN: 15 Total Hours x 100 Applicants = 1,875 Hours

ANNUAL COSTS

(a) Management: 1.0 hours x $76 x 100 applicants = $ 7,600

(b) Technical: 13.0 hours x $55 x 100 applicants = $71,500
(c) Clerical: 1.0 hours x $25 x 100 applicants = $ 2,500
Total = $81,600

Annual *Agency* Burden/Cost Estimates for Notifications

	Burden Hours per year			
Collection Activities	**Management $76/hr.**	**Technical $55/hr.**	**Clerical $25/hr.**	**Costs**
answer registrant's questions		8		$440
review notifications	25	190		$12350
record notifications		6		$330
analyze notifications		245		$13475
store notification information		8		$440
TOTAL	25	457		$27,035

6(d). Bottom Line Hours And Costs / Master Table

MASTER TABLE FOR EUPs

	TOTAL	
	Hours	Costs
Respondent Burden/Cost Estimates:	1,010	$75,790
Agency Burden/Cost Estimates:	1,500	$81,600

6(e). Reasons For Changes In Burden

The burden hours of 10.10 hours per respondent for EUPs remains the same from the previous ICR. The cost, however, has increased due to current, more realistic labor rates supplied by the Bureau of Labor Statistics.

The burden hours for Notifications has changed from the previous ICR from 818 hours to 552 hours. The decrease in hours comes from the one-time rule familiarization burden which is no longer

needed. There is an increase in number of respondents as the program has increased and more companies are persuing genetically modified pesticide products. Costs have changed with increased labor rates.

6(f). Burden Statement

The annual "respondent" (applicant) burden for the **Application for Experimental Use Permit to Ship and Use a Pesticide for Experimental Purposes Only** program is estimated to average 10.10 hours per EUP application, 78 hours per initial Notification, and 42 hours per Notification resubmission, including time for: reading relevant legislation, regulations, and instructions; planning activities; creating and gathering information; processing, compiling, and reviewing information; completing paperwork; recording disclosing, and displaying information; and storing, maintaining, and filing information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to, Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460.

Attachments